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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/403,724 | 12/20/1999 | PETER SONDEREGGER | 030708-035 | 7613 |

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EXAMINER

CHERNYSHEV, OLGA N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1646

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/403,724

Applicant(s)

SONDEREGGER, PETER

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/13/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-32 is/are pending in the application.
- 4a) Of the above claim(s) 17, 18 and 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 19, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 16, 19, 31 and 32 have been amended as requested in the amendment of Paper No. 20, 2003, filed on January 13, 2003. Claims 16-32 are pending in the instant application.

Claims 17, 18 and 20-30 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claims 16, 19, 31 and 32 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on January 13, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 16, 19, 31 and 32 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in section 3 of Paper No. 18. Briefly, the instant application has provided a description of isolated polypeptides, neurotrypsin of the human and neurotrypsin of the mouse. The instant application does not disclose the biological role of these proteins or their significance.

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Applicant submits that assertion of the specific substantial and credible utility of the claimed invention is clearly articulated "in original claims 3, 4, 10, 12 and 22 to 31. Among those utilities are the reduction or prevention of negative effects on brain tissue caused by epileptic seizures (claim 10); contributing to axonal regeneration and/or restoration of synaptic integrity and functions (claim 12); the amelioration of pathological pain syndromes (claim 22); ameliorating the learning and memory functions in healthy persons and persons with reduced learning and memory functions (claim 24); ameliorating certain psychiatric disorders (claims 27-29) or brain function deficiencies (claim 30)" (page 4, last paragraph of the Response). However, the Examiner fails to find support for such recitations within the above noted originally filed claims. Furthermore, according to the instant specification, utility of the claimed novel neurotrypsins appears to be asserted based on the similarity to the class of serine proteases and on the pattern of tissue distribution. Applicant fails to provide any evidence or sound scientific reasoning to support the assertion that the neurotrypsins of the instant invention, which have "only a 44% amino acid sequence identity" to the human plasmin (page 1, lines 33-34 of the instant specification) and "are expressed predominantly in neurons of those regions that are thought to play an important role in learning and memory functions" (page 14, lines 8-10), would have a specific, substantial and credible utility in any of the physiological functions, disorders or deficiencies recited on page 4 of the last paragraph of the Response. Applicant has failed to demonstrate that the administration of the claimed protein produces any particular physiological effect and has provided no rational scientific reasoning to support a conclusion that the administration of the claimed protein to a subject could be expected to produce a specific and desirable response.

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Applicant submits that Skolnick et al. article does not appear "to directly relate to Applicant's claims, specifically the isolated neurotrypsins according to SEQ ID NOS: 2 or 4 or the method for the development of pharmaceutical drugs based upon these sequence identifiers" (page 5, fourth paragraph of the Response). However, the reference of Skolnick et al. clearly teaches that similarity in the molecular structure does not necessarily and unequivocally lead to similarity of the function. This is especially true when differences in structure are greater than similarities (44%).

Applicant further argues that "a previous lack of success in treating disease or condition [...], should not, standing alone, serve as a basis for challenging an asserted utility under 35 U.S.C. 101" (page 4, second paragraph of the Response). The Examiner maintains a position that in the absence of knowledge of the specific biological role of these instant neurotrypsins, one skilled in the art clearly would not recognize immediately obvious patentable use of these novel molecular embodiments in "a method for the development of pharmaceutical drugs" (claim 19), for example, because the instant specification fails to describe any specific and credible affiliation of the instant compounds with any pathological condition. Furthermore, a skilled artisan would not identify the pharmacological benefit or physiological significance of inhibition or enhancement of "the catalytic activity of the coded proteins" (claim 31) because the instant specification fails to describe what is the specific function of the instant neurotrypsins.

Because the instant specification does not disclose a credible "real world" use for the instant neurotrypsin proteins then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. Claims 16, 19, 31 and 32 are also rejected under 35 U.S.C. 112, first paragraph for reasons of record in section 4 of Paper No. 18. Briefly, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 16 and 19 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16 and 19 are indefinite and confusing for reciting "[i]solated neurotrypsins", as in claim 16 or "isolated proteins", as in claim 19 for reasons of record in section 6 of Paper No. 18. Applicant argues that "[a]s amended, Claims 16 and 19 refer to the sequences of SEQ ID NOS:2 or 4 in the alternative" (page 6, sixth paragraph). This has not been found to be persuasive because the claims still appear to be directed to a mixture of polypeptides of the same or different sequences.

Conclusion

8. No claim is allowed.

9. This application contains claims drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

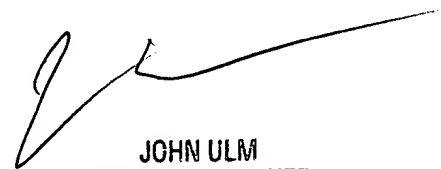
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signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *OC*
March 21, 2003



JOHN ULM
PRIMARY EXAMINER
GROUP 1800